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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,877

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Jonathan Henry Ellis

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SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

MACFARLANE, STACEY NEE

ART UNIT

PAPER NUMBER

1649

NOTIFICATION DATE

DELIVERY MODE

01/07/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No. 10/583,877	Applicant(s) ELLIS ET AL.	
	Examiner STACEY MACFARLANE	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,9-20,22,24-34 and 36 is/are pending in the application.
- 4a) Of the above claim(s) 4,6,7,9,10,14,15,17,18,20,22 and 24-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,11-13,16,19,34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 1, 2, 5, 11-13 and 16 have been amended, claims 3 and 35 have been cancelled, and claims 34 and 36 have been newly added as requested in the sequential amendments filed on June 3, 2008 and July 7, 2009, both filed after the first action on the merits mailed March 3, 2008. Following the amendment, claims 1, 2, 4-7, 9-20, 22, 24-34 and 36 are pending in the instant application.

Claims 4, 6, 7, 9, 10, 14, 15, 17, 18, 20, 22 and 24-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant elected without traverse the in the Paper filed on December 10, 2007.

Claims 1, 2, 5, 11-13, 16, 19, 34 and 36 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on June 3, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101 (Withdrawn)

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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As currently amended to recite an “isolated” antibody, the rejection of Claims 1-3, 5, 8, 13, 16 and 19 under 35 U.S.C. 101 is withdrawn.

Claim Rejections - 35 USC § 112 (Withdrawn)

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The current amendments have overcome the rejections of Claims 1-3, 5, 8, 11-13, 16 and 19 under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 112 (Withdrawn)

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 8 has been cancelled, thus the rejection under 35 U.S.C. 112, first paragraph, is moot.

Claim Rejections - 35 USC § 102 (Withdrawn)

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. As currently amended, the rejection of Claims 1-3, 11 and 19 under 35 U.S.C. 102(b) as being anticipated by Caroni et al. (1988), as evidenced by Zander et al. (2007) is withdrawn.

11. As amended the rejection of Claim 12 under 35 U.S.C. 102(b) as being anticipated by Fiedler et al.(2002) is withdrawn.

New Grounds – Necessitated by Amendment

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1, 2, 5, 11-13, 16, 19, 34 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to recite an antibody comprising each of the CDRs set forth in SEQ ID NOs: 1, 2, 3, 4, 5, 6 “or an analog of any CDR wherein the amino acid sequence of said CDR is modified by one amino acid”, which binds and “neutralises human NOGO-A”. Claims 2, 5, 11-13, 16, 19, 34 and 36 are dependent from Claim 1 and do not further limit the CDR “analog[s]”, and are therefore included in

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the rejection. The claims do not require that the CDR “analogs” with a modified amino acid possess any particular conserved structure or other distinguishing feature. Thus, the claims are drawn to a genus of molecules and are not limited to molecules with known structure. The analogs are further defined only by the functions of retaining the same antigen binding specificity and neutralizing ability. The instant specification fails to describe the entire genus of molecules that are encompassed by these claims.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant is in possession of specific examples of light chain CDR sequences and heavy chain CDR sequences (i.e. CDRs comprising SEQ ID NOs: 1-6). The claims, however, encompass analogs of those sequences that have been modified by one amino acid. There is no teaching within the disclosure identifying what amino acids can be varied within the CDR sequences and provide for retained binding and neutralization of human NOGO-A. Therefore, the claims are drawn to a genus of antibodies comprising analog CDR regions, and the specification does not adequately describe the encompassed genus.

In order to provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product,

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or any combination thereof. In the instant case, the only factor present in the claim is a recitation of binding and neutralization activity. There is not even identification of any particular portion of the CDR structures that must be conserved for said activity. Neither the prior art nor the instant disclosure define sufficient representative antibodies comprising said analogs which are sufficient to retain the claimed activity. Thus, the specification does not provide a representative number of species for the recited genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus of antibodies comprising analog CDR sequences.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, the court clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the structure of the encompassed analog CDRs which bind and neutralize human NOGO-A, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of identifying activity. Adequate written description requires more than a mere recitation of functional activity as part of the invention and a reference to a potential method of isolating or screening. The compound itself is required. See

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Fiers v Revel, 25 USPQ2d 1601 at 1601 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, claims 1, 2, 5, 11-13, 16, 19, 34 and 36 are rejected for failing to meet the written description requirement of 35 U.S.C. 112, first paragraph.

Allowable Subject Matter

14. Claims 1, 2, 5, 11-13, 16, 19, 34 and 36 appear to be free of the prior art and would be allowable if rewritten to overcome the issues under 35 U.S.C. 112, first paragraph.

Conclusion

15. No Claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-R 5:45 to 3:30, TELEWORK-Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649

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